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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,548	07/16/2003	Joel D. Oxman	57179US004	8448

32692 7590 09/27/2006

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EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,548	OXMAN ET AL.	
	Examiner	Art Unit	
	Frederick Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-15 and 18-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-15 and 18-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Previous Rejections

Unless specifically maintained infra, all previous rejections are withdrawn.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1, 4-15 and 18-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Rennie et al (US Pub. 2004/0033260).

The prior art discloses aqueous compositions comprising 0.1 to 30 percent by weight (see paragraph [0064]) thermoreversible polymer, which is preferably "Lutrol F-127", *i.e.*, Pluronic F-127, the same viscosity modifier used in the working examples of the instant specification. See paragraphs [0072] and [0091]. The compositions are nasally administered via pump sprayers and pressurized sprayers (paragraph [0016]) the latter containing liquid aerosol propellants (paragraph [0039].)

The term "dental", as used to characterize the instantly claimed compositions, is a purely functional recitation which only requires that a given composition be able to be used in the oral cavity (where it would contact teeth). The prior art compositions, although administered nasally, are certainly capable of being used in the oral cavity and thus can be considered functional "dental compositions" as well, and indeed they specifically contain many components commonly used in dentifrices, *e.g.*, humectant polyols (paragraph [0039]), flavors and sweeteners (paragraph [0042]), sodium bicarbonate (paragraph [0077]), chelating agents such as EDTA (paragraph [0079]), and antimicrobials/preservatives such as benzalkonium chloride (paragraph [0083]). Other adjuvants claimed instantly are disclosed as well, *e.g.*, zinc salt medicaments and organic acids (paragraphs [0033], [0042] and [0058]).

2) Claims 18, 19 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Kramaric et al (EPA 0 551 626).

The instant claims disclose "dental" compositions which are "capable of" being sprayed as a fine mist "into the oral environment". The prior art discloses aqueous compositions (solutions, which are thus "capable" of being sprayed as a fine mist) comprising 10 to 30 percent by weight thermoreversible poloxamer, which is preferably "Pluronic F-127", *i.e.*, Pluronic F-127, the same viscosity modifier used in the working examples of the instant specification. See claim 1 of the prior art; see also the compositions set forth in tables at pages 6, 7 and 9-12 therein. The compositions are orally administered, *i.e.*, are functionally also "dental" compositions. See page 8, line 10. Various additives corresponding to those recited instantly are included as well, including

bases (acid neutralizers) such as sodium hydroxide (see page 7, lines 50-55; see also claim 17); sodium chloride (a salt: see page 7, line 11); antibacterial/antiinfective agents such as benzalkonium chloride (page 8 lines 36-49); local anesthetics such as lidocaine (page 8, line 45); acetylsalicylic acid (both a "medicament" and an acid: see page 8, line 49); antifungal agents (page 8, line 51); and cosmetic agents such as peroxides (page 9, line 13).

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4-15, 20-29 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramaric et al (EPA 0 551 626) in view of Hill et al (USP 4,950,479).

The primary reference is discussed in subsection "2)" of the "Anticipation" rejection supra, and differs from the instant claims in its silence regarding administration via spray/aerosol devices, or compositions containing propellants. The primary reference is specifically concerned with increasing the coating coverage of the oral site treated, thereby increasing bioavailability of the active agent contained therein. See page 5, lines 28-31.

The secondary reference discloses using portable delivery systems, such as pumps, to deliver oral cleaning and/or coating compositions for the treatment of various oral conditions including "dental" conditions such as plaque and more general oral conditions such as dry mouth (see claim 2 of the patent). Preferred dispensing means are metered pump sprays and metered aerosol valve systems. (One skilled in the art knows that such devices contain propellants; see USP 4,863,073 (Burt et al) and USP 4,506,803 (Franklin et al), which are cited as illustrating the state of the aerosol art prior to filing of the instant application). The reference teaches that administration of oral care

compositions via metered aerosols is advantageous insofar as they permit individual dosages to be administered in a tight spray pattern targeted toward the tip of the tongue, which the user naturally tends to immediately rub over the surfaces of the mouth, thereby assisting in deployment of the cleaning and/or coating composition throughout the oral cavity. See column 5,lines 40-57, and column 8, lines 64-68. The secondary reference differs from the instant claims insofar as it does not specify thermoreversible compositions.

It would have been obvious to have administered the coating compositions of the primary reference via a metered aerosol device, motivated by the desire to optimize coverage of the affected site by maximizing deployment by the user throughout the oral cavity as taught by the secondary reference.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached on Monday-Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614